

Structured Product Labeling (SPL) OTC Sub-team Teleconference
September 13, 2010, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Gail Burke, Procter & Gamble
-  Amy Deuchler, Medline Industries, Inc.
-  Iris Feliciano, Tris Pharma
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Maureen Kapustynski, Cadbury
-  Julie Kim, Pfizer Consumer Healthcare
-  Mark Land, Boiron, Inc.
-  Debra Lehnus, Prestige Packaging, Inc.
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Paula Markert, GlaxoSmithKline (sub-team leader)
-  LuAnn Mays, Procter & Gamble
-  Ann Mitchell, Sandoz, Inc. (*for Michele Hewitt*)
-  Diane O'Grady, Purdue Pharma, L. P.
-  Kathy Olgers, Perrigo Company
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technology & Information Services, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Victor Singh, Sandoz (*for Michele Hewitt*)
-  Lonnie Smith, U.S. FDA
-  Carl Strotz, Pfizer Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Cynthia Thompson, Kimberly-Clark Corporation
-  Tonya Tucker, Perrigo Company
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Marie Waller, Oraceutical, LLC
-  JoAnn Witek, Consultant
-  Elise Wolfe, Combe, Inc.
-  Reena Zade, Dr. Reddy's Laboratories, Inc.
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: October 11, 2010, 1:00pm ET (unless cancelled)

III. Discussion

A. Lonnie Smith, FDA – Update on FDA Validation Procedures

- Although FDA currently does not provide drug listing information for posting on the DailyMed website, listing info is available via Freedom of Information Act (FOIA) and is being used by third parties. Therefore, one of FDA's goals is to ensure the info is as accurate as possible and one step in accomplishing this goal is continually improving the validation procedures.
- Validation of the regulatory citation for OTC monograph drugs for at least one of the active ingredients (AIs) cited will be done. No new information is required; it is simple confirmation that the appropriate citation/s has been included in the listing file.
- Companies should ensure they are providing the correct section headings for OTC product listings. Having the correct information will enhance search capabilities within the database.
- Validation procedures may be updated as appropriate. While FDA will provide notice to companies about the changes, implementation delays are unlikely to minimize any potential negative impact on patient/consumer safety.

B. Listing Issues

- Delisting – for product listings that have never been filed electronically, those products can be delisted by emailing a spreadsheet to FDA. Listing information submitted electronically will require electronic delisting and files submitted in R3 format will require updating to R4 format in order to remove the DailyMed file. (See attached minutes from ER/DL teleconference for additional information.)
- Active Pharmaceutical Ingredients (APIs)/Inactive Ingredients – discussions within the agency are ongoing as to the appropriate way to provide API and inactive ingredient information in the listing files. Training of the import staff continues but will take time to complete. All import staff should have access to the FDA e-List database to search for product listing information.
- Validation Procedures for Business Operations – assuming that the site has been registered electronically, FDA will assist companies if there is an issue with listing files failing validation due to the type/s of business operations listed (be sure to include the DUNS in the message to FDA). The preferred option is for companies to contact their business partners to update the establishment registration info but the agency will help if a product is held at the border or there is a reason why a company has been unable to resolve the problem directly through established business relationships.

C. Open Discussion

- The implementation guide for devices is out, a pilot program has been announced by FDA, and the SPL Device Sub-team is actively engaged (*see IV.E. below*).
- The broad message (circulated automatically last week) regarding the Gateway being down should not have any impact on submissions through production accounts.
- Files that have been previously accepted through the Gateway are not affected by updates to the validation procedure. However, if the file is changed and resubmitted, it must pass all of the current validation requirements regardless of whether or not the information changed (*i.e.*, the file must pass all current validation rules).
- A potential contact to obtain a list of your company's products listed with active NDCs is Linda Kibler (linda.kibler@fda.hhs.gov).
- There was an inquiry regarding the monograph citation for the OTC product Emetrol. It was noted that the presence of an NDC and/or drug facts on product does not mean the product is a drug product. No definitive answer was identified during the call but the citation in the listing file is part 357.

IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA SPL R4 Training Sessions** – Please visit website for updated information regarding training courses.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- B. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)

Telephone number: 1-866-775-9435

Participant passcode: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

NOTE: FDA Technical Q&A sessions are no longer held on Wednesdays.

Please visit the SPL Wiki page to access FDA's SPL R4 eBook Training Documents (<http://spl-work-group.wikispaces.com/>)

- C. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 517342

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

- D. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER PATRICIA L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

- E. **SPL Generics Sub-team calls:** Not currently holding regular calls.
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

- F. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST
Please email Sub-team leader Myron Finseth (myron.finseth@medtronic.com) if you want to join this sub-team.

Telephone Number: 770-657-9270
Participant passcode: 745896

Please separate attachment for additional information.

G. SPL Usage Discussion Group

Please email or call Terry Brunone (Theresa.M.Brunone@gsk.com; +1-215-751-3210) or Gary Saner (gsaner@reedtech.com; +1-610-731-7192) if you wish to join the discussion group.

Their first meeting was August 31st and the next meeting will be September 21st. (See summary provided as separate attachment.)

During the September meeting (1:00 - 2:00 pm ET), Pablo R. Perillan, M.D., Ph.D., of Medicos Consultant LLC, will be speaking on the topic of “SPL in the Clinical Environment.”

Telephone Number: 800-963-3556 (international +1-404-602-0792)
Participant passcode: 1921 052#

Please separate attachment for additional information.

MDH/09-17-10

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